

Initials: CSE/DES/cmm      Docket No.: 0975.1005-013      Date: October 30, 2001

This is to acknowledge receipt of the following documents each filed under Certificate of Mailing Procedure 37 C.F.R. 1.8:

☒ INFORMATION DISCLOSURE STATEMENT      w/copy  
☒ Form PTO-1449 pp 1-7      ☒ with references as noted in 1449  
☐ Authorization to Charge all Fees  
☒ Other Copy of Pending Application and claims for 0975.1005-006

Applicants:      Junming Le, et al.  
Application No.: 09/927,703      Filed: August 10, 2001  
Title:      ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR..

Date received by the PTO:



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C:\SH\DES\emm  
10/29/01

PATENT APPLICATION  
DOCKET NO.: 0975.1005-013

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghayeb, David M. Knight and  
Scott Siegel

Application No.: 09/927,703 Group Art Unit: 1642

Filed: August 10, 2001 Examiner: Not Assigned

Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR NECROSIS  
FACTOR

| CERTIFICATE OF MAILING  |                            |
|---|----------------------------|
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, Washington, D.C. 20231 |                            |
| on <u>10/30/01</u>  | <u>Christina McSweeney</u> |
| Date  | Signature                  |
| <u>Christina McSweeney</u>  |                            |
| Typed or printed name of person signing certificate   |                            |

**OFFICIAL**

PG 9/14/03

INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

This Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

09/927,703

-2-

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Copies of cited references are enclosed except those entered in prior applications, U.S. Application No. 09/756,398 and Application No. 09/133,119, to which priority under 35 U.S.C. 120 is claimed. The earlier applications contains copies of the cited references.
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) ☐ under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ the enclosed English language abstract.

- ☒ Applicant requests that the following pending applications be considered:

Examiner's  
Initials

\_\_\_\_\_  
U.S. Patent Application No. 09/756,398, by Junming Lo, Jan Vilcek, Peter Daddona, John Ghayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-006

09/27,703

-3-

U.S. Patent Application No. 09/756,161, by Junming Le, Jan Vilcek, Peter Daddona, John Ghayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-007

U.S. Patent Application No. 09/756,301, by Junming Le, Jan Vilcek, Peter Daddona, John Ghayeb, David M. Knight and Scott Siegel, filed January 8, 2001, Docket No.: 0975.1005-008

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Examiner

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Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☒ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. 09/756,398, to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

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Dated: October 29, 2001

Received from <1 978 341 0136> at 9/29/03 12:11:47 PM [Eastern Daylight Time]

DOC ID NO.: :OPMA\NHODMA\iMan 251118;1

Sheet 1 of 7

|   |    |  |           |                                      |       |                               |                                  |
|---|----|--|-----------|--------------------------------------|-------|-------------------------------|----------------------------------|
| PTO-1449 REPRODUCED   |    |  |           | ATTORNEY DOCKET NO.<br>0975.1005-013 |       | APPLICATION NO.<br>09/927,703 |                                  |
| INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION<br><br>October 29, 2001<br><br>(Use several sheets if necessary) |    |  |           | APPLICANT<br>Junming Le, et al.      |       |                               |                                  |
|   |    |  |           | FILING DATE<br>August 10, 2001       |       | GROUP<br>1642                 |                                  |
| U.S. PATENT DOCUMENTS   |    |  |           |                                      |       |                               |                                  |
| EXAM-<br>INER<br>INI-<br>TIAL   |    | DOCUMENT NUMBER  | DATE      | NAME                                 | CLASS | SUB-<br>CLASS                 | FILING DATE<br>IF<br>APPROPRIATE |
|   | AA | 4,603,106  | 07/29/86  | Cerami et al.                        | 435   | 7                             |                                  |
|   | AB | 4,822,776  | 04/18/89  | Cerami et al.                        | 514   | 21                            |                                  |
|   | AC | 5,658,570  | 08/19/97  | Newman et al.                        | 424   | 184.1                         |                                  |
|   | AD | 5,750,105  | 5/12/98   | Newman et al.                        | 424   | 133.1                         |                                  |
|   | AE | 5,231,024  | 7/27/93   | Moeller et al.                       | 435   | 240.27                        |                                  |
|   | AF | 5,888,511  | 03/30/99  | Skurkovich et al.                    | 424   | 145.1                         |                                  |
|   | AG | 5,958,413  | 09/28/99  | Anagnostopoulos et al.               | 424   | 178.1                         |                                  |
|   | AH | 5,993,833  | 11/30/99  | DeLacharriere et al.                 | 424   | 401                           |                                  |
|   | AI | 5,342,613  | 08/30/94  | Croaven et al.                       | 424   | 85.1                          |                                  |
|   | AJ | 6,190,691 B1   | 02/20/01  | Mak                                  | 424   | 449                           |                                  |
| FOREIGN PATENT DOCUMENTS  |    |  |           |                                      |       |                               |                                  |
|   |    | DOCUMENT NUMBER  | DATE      | COUNTRY                              | CLASS | SUB-<br>CLASS                 | TRANSLATION<br>YES NO            |
|   | AL | 0212489A2  | 04 MAR 87 | EPO                                  |       |                               |                                  |
|   | AM | 0218868A2  | 22 APR 87 | EPO                                  |       |                               |                                  |
|   | AN | 0288068A2  | 26 OCT 88 | EPO                                  |       |                               |                                  |
|   | AO | 0308378A2  | 22 MAR 89 | EPO                                  |       |                               |                                  |
|   | AP | 0380068A1  | 01 AUG 90 | EPO                                  |       |                               |                                  |
|   | AQ | 0393438A3  | 24 OCT 90 | EPO                                  |       |                               |                                  |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)  |    |  |           |                                      |       |                               |                                  |
|   | AR | Beutler, B. et al., "Identity of tumour necrosis factor and the macrophage-secreted factor cachectin," <i>Nature</i> , 316:552-554 (1985).                             |           |                                      |       |                               |                                  |
|   | AS | Beutler, B. et al., "Passive Immunization Against Cachectin/Tumor Necrosis Factor Protects Mice from Lethal Effect of Endotoxin," <i>Science</i> , 229:869-871 (1985). |           |                                      |       |                               |                                  |
|   | AT | Morrison, Sharie L., "Transfectomas Provide Novel Chimeric Antibodies," <i>Science</i> , 229:1202-1207 (1985).   |           |                                      |       |                               |                                  |
| EXAMINER  |    |  |           | DATE CONSIDERED                      |       |                               |                                  |

Sheet 2 of 7

|  |     |   |           |                                      |       |                               |                                  |
|--|-----|---|-----------|--------------------------------------|-------|-------------------------------|----------------------------------|
| PTG-1449 REPRODUCED  |     |   |           | ATTORNEY DOCKET NO.<br>0975.1005-013 |       | APPLICATION NO.<br>09/927,703 |                                  |
| INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION                   |     |   |           | APPLICANT<br>Junming Le, et al.      |       |                               |                                  |
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| U.S. PATENT DOCUMENTS  |     |   |           |                                      |       |                               |                                  |
| EXAM-<br>INER<br>INI-<br>TIAL  |     | DOCUMENT NUMBER   | DATE      | NAME                                 | CLASS | SUB-<br>CLASS                 | FILING DATE<br>IF<br>APPROPRIATE |
| FOREIGN PATENT DOCUMENTS   |     |   |           |                                      |       |                               |                                  |
|  |     | DOCUMENT NUMBER   | DATE      | COUNTRY                              | CLASS | SUB-<br>CLASS                 | TRANSLATION<br>YES NO            |
|  | AL1 | 0398327A1   | 22 NOV 90 | EPO                                  |       |                               |                                  |
|  | AM2 | 0412486A1   | 13 FEB 91 | EPO                                  |       |                               |                                  |
|  | AN3 | 0433900A1   | 26 JUN 91 | EPO                                  |       |                               |                                  |
|  | AO2 | 0526905A2   | 10 FEB 93 | EPO                                  |       |                               |                                  |
|  | AP2 | WO91/02078  | 21 FEB 91 | PCT                                  |       |                               |                                  |
|  | AQ2 | WO92/07076  | 30 APR 92 | PCT                                  |       |                               |                                  |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.) |     |   |           |                                      |       |                               |                                  |
|  | AU  | Liang, Chi-Ming et al., "Production and Characterization of Monoclonal Antibodies Against Recombinant Human Tumor Necrosis Factor/Cachectin," <i>Biochem. &amp; Biophys. Res. Comm.</i> , 137(2):847-854 (1986).                              |           |                                      |       |                               |                                  |
|  | AV  | Hirai, Makoto et al., "Production and characterization of monoclonal antibodies to human tumor necrosis factor," <i>J. of Immun. Methods</i> , 96:57-62 (1987).   |           |                                      |       |                               |                                  |
|  | AW  | Piquet, Pierre-Francois et al., "Tumor Necrosis Factor/Cachectin is an Effector of Skin and Gut Lesions of the Acute Phase of Graft-vs.-Host Disease," <i>J. Exp. Med.</i> , 166:1280-1289 (1987).  |           |                                      |       |                               |                                  |
|  | AX  | Moager, Anthony et al., "Preparation and Characterization of Monoclonal Antibodies Directed Against Antigenic Determinants of Recombinant Human Tumour Necrosis Factor (rTNF)," <i>Hybridoma</i> , 6(3):305-311 (1987).                       |           |                                      |       |                               |                                  |
|  | AY  | Fendly, Brian M. et al., "Murine Monoclonal Antibodies Defining Neutralizing Epitopes on Tumor Necrosis Factor," <i>Hybridoma</i> , 6(4):359-370 (1987).  |           |                                      |       |                               |                                  |
|  | AZ  | Bringman, Timothy S. and Aggarwal, Bharat B., "Monoclonal Antibodies to Human Tumor Necrosis Factors Alpha and Beta: Applications for Affinity Purification, Immunoassays, and as Structural Probes," <i>Hybridoma</i> , 6(5):489-507 (1987). |           |                                      |       |                               |                                  |
|  | AR2 | Tracey, Kevin J. et al., "Anti-cachectin/TNF monoclonal antibodies prevent septic shock during lethal bacteraemia," <i>Nature</i> , 330:662-664 (1987).   |           |                                      |       |                               |                                  |
|  | AS2 | Nagai, M. et al., "Antibody to tumor necrosis factor (TNF) reduces endotoxin fever," <i>Experientia</i> , 44:606-607 (1988).  |           |                                      |       |                               |                                  |
| EXAMINER   |     |   |           | DATE CONSIDERED                      |       |                               |                                  |

Sheet 3 of 7

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| PTO-1449 REPRODUCED   |     |  | ATTORNEY DOCKET NO.<br>0975.1005-013 |                 | APPLICATION NO.<br>09/927,703 |               |
| INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION<br><br>October 29, 2001<br><br>(Use several sheets if necessary) |     |  | APPLICANT<br>Junming Le, et al.      |                 |                               |               |
|   |     |  | FILING DATE<br>August 10, 2001       |                 | GROUP<br>1642                 |               |
| U.S. PATENT DOCUMENTS   |     |  |                                      |                 |                               |               |
| EXAM-<br>INER<br>INI-<br>TIAL   |     | DOCUMENT NUMBER  | DATE                                 | NAME            | CLASS                         | SUB-<br>CLASS |
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| FOREIGN PATENT DOCUMENTS  |     |  |                                      |                 |                               |               |
|   |     | DOCUMENT NUMBER  | DATE                                 | COUNTRY         | CLASS                         | SUB-<br>CLASS |
|   | AL3 | WO92/13095   | 06 AUG 92                            | PCT             |                               |               |
|   | AM3 | 0260610A2  | 23 MAR 88                            | EPO             |                               |               |
|   | AN3 | 91/09967   | 11 JUL 91                            | PCT             |                               |               |
|   | AO3 | 0351789A2  | 24 JAN 90                            | EPO             |                               |               |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)  |     |  |                                      |                 |                               |               |
|   | AT2 | Shimamoto, Yoshinori et al., "Monoclonal antibodies against human recombinant tumor necrosis factor: prevention of endotoxic shock," <i>Immunology Letters</i> , 17:311-318 (1988).  |                                      |                 |                               |               |
|   | AU3 | Di Giovine, Francesco, S. et al., "Tumour necrosis factor in synovial exudates," <i>Annals of the Rheumatic Diseases</i> , 47:768-772 (1988).  |                                      |                 |                               |               |
|   | AV2 | Collins, M.S. et al., "Immunoprophylaxis of Polymicrobial Cellulitis with a Human Monoclonal Antibody Against Lipopolysaccharide Antigen of <i>Pseudomonas aeruginosa</i> ," Abstract E-63, <i>Abstracts of Annual Meeting 1989</i> .        |                                      |                 |                               |               |
|   | AW2 | Exley, A.R. et al., "Monoclonal Antibody (Map) to Recombinant Human Tumour Necrosis Factor (rhTNF) in the Prophylaxis and Treatment of Endotoxic Shock in Cynomolgus Monkeys," <i>Medical Research Society</i> , Abstract 184, p. 50 (1989). |                                      |                 |                               |               |
|   | AX2 | Cross, A.S. et al., "Pretreatment with Recombinant Murine Tumor Necrosis Factor $\alpha$ /Cachectin and Murine Interleukin 1 $\alpha$ Protects Mice from Lethal Bacterial Infection," <i>J of Exp Med.</i> , 169:2021-2027 (1989).           |                                      |                 |                               |               |
|   | AY2 | Engelmann, Hartmut et al., "A Tumor Necrosis Factor-binding Protein Purified to Homogeneity from Human Urine Protects Cells from Tumor Necrosis Factor Toxicity," <i>J. of Bio. Chem.</i> , 264(20):11974-11980 (1989).                      |                                      |                 |                               |               |
|   | AZ2 | Kawasaki, Hajime et al., "Analysis of Endotoxin Fever in Rabbits by Using a Monoclonal Antibody to Tumor Necrosis Factor (Cachectin)," <i>Infection and Immunity</i> , 57(10):3131-3135 (1989).  |                                      |                 |                               |               |
| EXAMINER  |     |  |                                      | DATE CONSIDERED |                               |               |

|   |     |   |           |                                      |       |                               |                                  |
|---|-----|---|-----------|--------------------------------------|-------|-------------------------------|----------------------------------|
| PTO. 1419 REPRODUCED  |     |   |           | ATTORNEY DOCKET NO.<br>0975.1005-013 |       | APPLICATION NO.<br>09/927,703 |                                  |
| INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION<br>October 29, 2001<br>(Use several sheets if necessary) |     |   |           | APPLICANT<br>Junming Le, et al.      |       |                               |                                  |
|   |     |   |           | FILING DATE<br>August 10, 2001       |       | GROUP<br>1642                 |                                  |
| U.S. PATENT DOCUMENTS   |     |   |           |                                      |       |                               |                                  |
| EXAM-<br>INER<br>INI-<br>TIAL   |     | DOCUMENT NUMBER   | DATE      | NAME                                 | CLASS | SUB-<br>CLASS                 | FILING DATE<br>IF<br>APPROPRIATE |
|   |     |   |           |                                      |       |                               |                                  |
| FOREIGN PATENT DOCUMENTS  |     |   |           |                                      |       |                               |                                  |
|   |     | DOCUMENT NUMBER   | DATE      | COUNTRY                              | CLASS | SUB-<br>CLASS                 | TRANSLATION<br>YES NO            |
|   | AP3 | 0350690A2   | 17 JAN 90 | RPO                                  |       |                               |                                  |
|   | AQ3 | 90/00902  | 08 FEB 90 | PCT                                  |       |                               |                                  |
|   | AL4 | WO 92/11383   | 09 JUL 92 | PCT                                  |       |                               |                                  |
|   | AN4 | WO 93/02108   | 4 FEB 93  | PCT                                  |       |                               |                                  |
|   | AN4 | WO 92/16553   | 19 MAR 92 | PCT                                  |       |                               |                                  |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)  |     |   |           |                                      |       |                               |                                  |
|   | AR3 | Fong, Yuman et al., "Antibodies to Cachectin/Tumor Necrosis Factor Reduce Interleukin 1 $\beta$ and Interleukin 6 Appearance During Lethal Bacteremia," <i>J. Exp. Med.</i> , 170:1627-1633 (1989).   |           |                                      |       |                               |                                  |
|   | AQ3 | Von Asmuth, E.J.U. et al., "Tumour Necrosis Factor Alpha (TNF- $\alpha$ ) and Interleukin 6 in a Zymosan-Induced Shock Model," <i>Scand. J. Immunol.</i> , 32:313-319 (1990).   |           |                                      |       |                               |                                  |
|   | AT3 | Herve, P. et al., "Monoclonal Anti TNF $\alpha$ Antibody for the Treatment of Severe Acute GvHD in Humans," Abstract 3.25, <i>Lymphoma Res.</i> 9:591 (1990).   |           |                                      |       |                               |                                  |
|   | AU3 | Silva, Ayona T. et al., "Prophylactic and Therapeutic Effects of a Monoclonal Antibody to Tumor Necrosis Factor- $\alpha$ in Experimental Gram-Negative Shock," <i>J. of Infectious Diseases</i> , 162:421-427 (1990).                                |           |                                      |       |                               |                                  |
|   | AV3 | Opal, Steven M. et al., "Efficacy of a Monoclonal Antibody Directed Against Tumor Necrosis Factor in Protecting Neutropenic Rats from Lethal Infection with <i>Pseudomonas aeruginosa</i> ," <i>J. of Infectious Diseases</i> , 161:1148-1152 (1990). |           |                                      |       |                               |                                  |
|   | AW3 | Tavernier, Jan et al., "Analysis of the Structure-Function Relationship of Tumour Necrosis Factor. Human/Mouse Chimeric TNF Proteins: General Properties and Epitope Analysis," <i>J. Mol. Biol.</i> , 211:493-501 (1990).                            |           |                                      |       |                               |                                  |
|   | AX3 | Lucas, R. et al., "Generation and characterization of a neutralizing rat anti-rm TNF- $\alpha$ monoclonal antibody," <i>Immunology</i> , 71:218-223 (1990).   |           |                                      |       |                               |                                  |
|   | AY3 | Hinshaw, L.B. et al., "Survival of Primates in LD <sub>100</sub> Septic Shock Following Therapy with Antibody to Tumor Necrosis Factor (TNF $\alpha$ )," <i>Circulatory Shock</i> , 30:279-292 (1990).  |           |                                      |       |                               |                                  |
| EXAMINER  |     |   |           | DATE CONSIDERED                      |       |                               |                                  |



|   |      |  |           |                                      |       |                               |                                  |
|---|------|--|-----------|--------------------------------------|-------|-------------------------------|----------------------------------|
| PTO-1449 REPRODUCED   |      |  |           | ATTORNEY DOCKET NO.<br>0975.1005-013 |       | APPLICATION NO.<br>09/927,703 |                                  |
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| EXAM-<br>INER<br>INI-<br>TIAL   |      | DOCUMENT NUMBER  | DATE      | NAME                                 | CLASS | SUB-<br>CLASS                 | FILING DATE<br>IF<br>APPROPRIATE |
|   |      |  |           |                                      |       |                               |                                  |
|   |      |  |           |                                      |       |                               |                                  |
| FOREIGN PATENT DOCUMENTS  |      |  |           |                                      |       |                               |                                  |
|   |      | DOCUMENT NUMBER  | DATE      | COUNTRY                              | CLASS | SUB-<br>CLASS                 | TRANSLATION<br>YES NO            |
|   | AOA  | O 867 509 A2   | 30 SEP 98 | EPO                                  |       |                               |                                  |
|   | AP4  | O 861 850 A1   | 02 SEP 98 | EPO                                  |       |                               |                                  |
| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)  |      |  |           |                                      |       |                               |                                  |
|   | AZ3  | Nophar, Yaron et al., "Soluble forms of tumor necrosis factor receptors (TNF-Rs). The cDNA for the type 1 TNF-R, cloned using amino acid sequence data of its soluble form, encodes both the cell surface and a soluble form of the receptor," <i>The EMBO Journal</i> , 9(10):3269-3278 (1990). |           |                                      |       |                               |                                  |
|   | AM4  | Engelmann, Martmut et al., "Two Tumor Necrosis Factor-binding Proteins Purified from Human Urine," <i>J. of Bio. Chem.</i> , 265(3):1531-1536 (1990).  |           |                                      |       |                               |                                  |
|   | AS4  | Verhoef, J. and Torensma, R., "Prospects for Monoclonal Antibodies in the Diagnosis and Treatment of Bacterial Infections," <i>Eur. J. Clin. Microbiol. Dis.</i> , 9(4):247-250 (1990).  |           |                                      |       |                               |                                  |
|   | AT4  | Loetscher, Hansruedi et al., "Molecular Cloning and Expression of the Human 55 kd Tumor Necrosis Factor Receptor," <i>Cell</i> , 61:351-359 (1990).  |           |                                      |       |                               |                                  |
|   | AU-1 | Schall, Thomas J. et al., "Molecular Cloning and Expression of a Receptor for Human Tumor Necrosis Factor," <i>Cell</i> , 61:361-370 (1990).   |           |                                      |       |                               |                                  |
|   | AV4  | Akama, Hideto et al., "Mononuclear Cells Enhance Prostaglandin E <sub>2</sub> Production of Polymorphonuclear Leukocytes via Tumor Necrosis Factor $\alpha$ ," <i>Biochemical and Biophysical Research Comm.</i> , 168(2):857-862 (1990).  |           |                                      |       |                               |                                  |
|   | AW4  | Exley, A.R. et al., "Monoclonal antibody to TNF in severe septic shock," <i>The Lancet</i> , 335:1275-1277 (1990).   |           |                                      |       |                               |                                  |
|   | AX4  | Möller, Achim et al., "Monoclonal Antibodies to Human Tumor Necrosis Factor $\alpha$ : In Vitro and In Vivo Application," <i>Cytokine</i> , 2(3):162-169 (1990).   |           |                                      |       |                               |                                  |
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| PTO-1449 REPRODUCED   |     |  |           | ATTORNEY DOCKET NO.<br>0975.1005-013 |       | APPLICATION NO.<br>09/927,703 |                                  |
| INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION<br><br>October 29, 2001<br><br>(Use several sheets if necessary) |     |  |           | APPLICANT<br>Junming Le, et al.      |       |                               |                                  |
|   |     |  |           | FILING DATE<br>August 10, 2001       |       | GROUP<br>1642                 |                                  |
| U.S. PATENT DOCUMENTS   |     |  |           |                                      |       |                               |                                  |
| EXAM-<br>INER<br>INITIAL  |     | DOCUMENT NUMBER  | DATE      | NAME                                 | CLASS | SUB-<br>CLASS                 | FILING DATE<br>IF<br>APPROPRIATE |
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| FOREIGN PATENT DOCUMENTS  |     |  |           |                                      |       |                               |                                  |
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|   | AL5 | 0 870 827 A2   | 14 OCT 98 | EPO                                  |       |                               |                                  |
|   | AMS | 0 706 795 A2   | 17 APR 96 | EPO                                  |       |                               |                                  |
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| EXAMINER  |     |  |           | DATE CONSIDERED                      |       |                               |                                  |

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| PTO-1449 REPRODUCED   |     | ATTORNEY DOCKET NO.<br>0975.1005-013   |           | APPLICATION NO.<br>09/927,703 |       |               |                                  |
| INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION<br><br>October 29, 2001<br><br>(Use several sheets if necessary) |     | APPLICANT<br>Junming Le, et al.  |           |                               |       |               |                                  |
|   |     | FILING DATE<br>August 10, 2001   |           | GROUP<br>1642                 |       |               |                                  |
| U.S. PATENT DOCUMENTS   |     |  |           |                               |       |               |                                  |
| EXAM-<br>INER<br>INI-<br>TIAL   |     | DOCUMENT NUMBER  | DATE      | NAME                          | CLASS | SUB-<br>CLASS | FILING DATE<br>IF<br>APPROPRIATE |
| FOREIGN PATENT DOCUMENTS  |     |  |           |                               |       |               |                                  |
|   |     | DOCUMENT NUMBER  | DATE      | COUNTRY                       | CLASS | SUB-<br>CLASS | TRANSLATION<br>YES NO            |
|   | AN5 | Q 706 795 A3   | 17 DEC 97 | EPO                           |       |               |                                  |
|   | A05 | WQ98/51344   | 19 NOV 98 | PCT                           |       |               |                                  |
|   | AP5 | W000/62790   | 26 OCT 00 | PCT                           |       |               |                                  |
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| EXAMINER  |     |  |           | DATE CONSIDERED               |       |               |                                  |

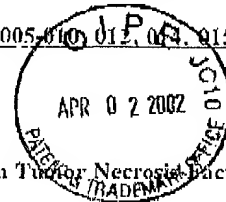
Initials: CSE/DES/JCZ(cmm) Docket No.: 0975.1005-013 Date:

This is to acknowledge receipt of the following documents each filed under Certificate of Mailing Procedure 37 C.F.R. 1.8:

☒ SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
 \_\_\_\_\_ w/copy  
 \_\_\_\_\_ Form PTO-1449 pp \_\_\_\_\_ with references as noted in 1449  
 \_\_\_\_\_ Authorization to Charge all Fees  
☒ Other \_\_\_\_\_ Copies of co-pending applications for 0975.1005-010, 011, 012, 013, 014, 015, 016, 017 & 018

Applicants: Junming Li, *et al.*  
 Application No.: 09/927,703 Filed: August 10, 2001  
 Title: Anti-TNF Antibodies and Peptides of Human Tumor Necrosis Factor

Date received by the PTO: ::OPIN\N\H\O\PM\AM\Manage;296257,1



@PFDesktop\ODMA\MHODMA\ age:289080;1  
AOC/DES/ICZ/cinn(rein)  
March 29, 2002

PATENT APPLICATION  
DOCKET NO.: 0975.1005-013

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and  
Scott Siegel

Application No.: 09/927,703 Group Art Unit: 1642

Filed: August 10, 2001 Examiner: Not Assigned

Title: ANTI-TNF ANTIBODIES AND PEPTIDES OF HUMAN TUMOR NECROSIS  
FACTOR

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| CERTIFICATE OF MAILING  |                      |
| I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to Assistant Commissioner for Patents, P.O. Box 2327, Arlington, VA 22202 |                      |
| on <u>3/24/02</u>   | <u>Stacy McGarry</u> |
| Date  | Signature            |
| <u>STACY MCGARRY</u>  |                      |

**OFFICIAL**

PG 9/29/03

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Assistant Commissioner for Patents  
P.O. Box 2327  
Arlington, VA 22202

Sir:

This Supplemental Information Disclosure Statement is submitted:

- ☐ under 37 CFR 1.129(a), or  
(First/Second submission after Final Rejection)
- ☒ under 37 CFR 1.97(b), or  
(Within any one of the following time periods: three months of filing national application (other than a CPA) or date of entry of the national stage in an international application; or before the mailing date of a first office action on the merits in a non-provisional application, including a CPA, or a Request for Continued Examination).
- ☐ under 37 CFR 1.97(c) together with either:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, or
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(After the 37 CFR 1.97(b) time period, but before final action or notice of allowance, whichever occurs first)
- ☐ under 37 CFR 1.97(d) together with:
- ☐ a Statement under 37 CFR 1.97(e), as checked below, and
- ☐ a \$180.00 fee under 37 CFR 1.17(p), or  
(Filed after final action or notice of allowance, whichever occurs first, but on or before payment of the issue fee)
- ☐ under 37 CFR 1.97(i):  
Applicant requests that the IDS and cited reference(s) be placed in the application filewrapper.  
(Filed after payment of issue fee)

09/27,703

-2-

Statement Under 37 CFR 1.97(e)

- ☐ Each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement; or
- ☐ No item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the undersigned, after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in 37 CFR 1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

Statement Under 37 CFR 1.704(d) (Patent Term Adjustment)

Applies to original applications (other than design) filed on or after May 29, 2000

- ☐ Each item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in § 1.56(c) more than thirty days prior to the filing of the Information Disclosure Statement.
- ☒ Enclosed herewith is form PTO-1449:
- ☐ Copies of the cited references are enclosed.
- ☒ Copies of cited references are enclosed except those entered in prior application, U.S. Application No. 09/756,398, to which priority under 35 U.S.C. 120 is claimed. [The earlier application contains copies of the cited references.]
- ☐ The listed references were cited in the enclosed International Search Report in a counterpart foreign application.
- ☐ The "concise explanation" requirement (non-English references) for reference(s) [ ] under 37 CFR 1.98(a)(3) is satisfied by:
- ☐ the explanation provided on the attached sheet.
- ☐ the explanation provided in the Specification.
- ☐ submission of the enclosed International Search Report.
- ☐ the enclosed English language abstract.

- ☒ Applicant requests that the following pending applications be considered:

Examiner's  
initials

- \_\_\_\_\_ U.S. Patent Application No. 09/766,535, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 18, 2001, Docket No.: 0975.1005-010
- \_\_\_\_\_ U.S. Patent Application No. 09/897,724, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed July 2, 2001, Docket No.: 0975.1005-012
- \_\_\_\_\_ U.S. Patent Application No. 10/010,229, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed December 7, 2001, Docket No.: 0975.1005-014
- \_\_\_\_\_ U.S. Patent Application No. 10/043,450, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-015

09/27,703

-3-

U.S. Patent Application No. 10/044,534, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-016

U.S. Patent Application No. 10/043,432, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-017

U.S. Patent Application No. 10/043,436, by Junming Le, Jan Vilcek, Peter Daddona, John Ghrayeb, David M. Knight and Scott Siegel, filed January 10, 2002, Docket No.: 0975.1005-018

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Date

- ☐ A copy of each above-cited application, including the current claims, is enclosed.
- ☒ A copy of each above-cited application, including the current claims, is enclosed, except those entered in prior application, U.S. Application No. 09/756,398, to which priority under 35 U.S.C. 120 is claimed.

The Examiner is requested to return a copy of the above list of pending applications indicating which references were considered with the next office communication.

It is requested that the information disclosed herein be made of record in this application.

Method of payment:

- ☐ A check for the fee noted above is enclosed, or the fee has been included in the check with the accompanying Reply. A copy of this Statement is enclosed.
- ☐ Please charge Deposit Account 08-0380 in the amount of \$[ ]. A copy of this Statement is enclosed.
- ☒ Please charge any deficiency in fees and credit any overpayment to Deposit Account 08-0380.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By

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Dated:

*March 27, 2002*

DOC ID NO.: 0975.1005-013

Sheet 1 of 3

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| PRO-1449 REPRODUCED<br><br>INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION<br><br>March 29, 2002<br>(Use several sheets if necessary) |     |  |           | ATTORNEY DOCKET NO.<br>0975.1005-013 |       | APPLICATION NO.<br>09/927,703 |                                      |
|  |     |  |           | APPLICANT<br>Junming Le, et al.      |       |                               |                                      |
|  |     |  |           | FILING DATE<br>August 10, 2001       |       | GROUP<br>1642                 |                                      |
| U.S. PATENT DOCUMENTS  |     |  |           |                                      |       |                               |                                      |
| EXAM-<br>INER<br>INT-<br>TIAL  |     | DOCUMENT NUMBER  | DATE      | NAME                                 | CLASS | SUB-<br>CLASS                 | FILING<br>DATE IF<br>APPROPRIA<br>TE |
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| FOREIGN PATENT DOCUMENTS   |     |  |           |                                      |       |                               |                                      |
|  |     | DOCUMENT NUMBER  | DATE      | COUNTRY                              | CLASS | SUB-<br>CLASS                 | TRANSLATI<br>ON<br>YES NO            |
|  | A05 | WO91/09967   | 11 JUL 91 | PCT                                  |       |                               |                                      |
|  | AL6 | 0486526B2  | 07 MAR 01 | EPO                                  |       |                               |                                      |
|  | AM6 | WO92/02190   | 10 JUN 92 | PCT                                  |       |                               |                                      |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)   |     |  |           |                                      |       |                               |                                      |
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| EXAMINER   |     |  |           | DATE CONSIDERED                      |       |                               |                                      |



Sheet 2 of 3

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| PTO-1419 REPRODUCED  |     | ATTORNEY DOCKET NO.<br>0975.1005-013   |      | APPLICATION NO.<br>09/927,703   |       |               |                                  |
| INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION                   |     |  |      | APPLICANT<br>Junming Le, et al. |       |               |                                  |
| March 29, 2002<br>(Use several sheets if necessary)                    |     |  |      | FILING DATE<br>August 10, 2001  |       |               |                                  |
| GROUP<br>1642  |     |  |      |                                 |       |               |                                  |
| U.S. PATENT DOCUMENTS  |     |  |      |                                 |       |               |                                  |
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|  | AZ7 | Lassalle, Ph., et al., "Potential Implication of Endothelial Cells in Bronchial Asthma," <i>Int Arch Allergy Appl Immunol</i> , 94:233-238 (1991).   |      |                                 |       |               |                                  |
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|  | AS8 | Eck, Michael J. and Sprang, Stephen R., "The Structure of Tumor Necrosis Factor- $\alpha$ at 2.6 Å Resolution," <i>J Biol Chem</i> , 264:17595-17605 (1989).                                   |      |                                 |       |               |                                  |
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|  | AU8 | Kamoyama, Koh-zoh, et al., "Convenient plasmid vectors for construction of chimeric mouse/human antibodies," <i>FEBS Lett</i> , 244:301-306 (1989).  |      |                                 |       |               |                                  |
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| PTO-1449 REPRODUCED   |     | ATTORNEY DOCKET NO.<br>0975.1005-013  |      | APPLICATION NO.<br>09/927,703 |       |               |                                  |
| INFORMATION DISCLOSURE CITATION<br>IN AN APPLICATION<br><br>March 29, 2002<br>(Use several sheets if necessary) |     | APPLICANT<br>Junming I.e, et al.  |      |                               |       |               |                                  |
|   |     | FILING DATE<br>August 10, 2001  |      | GROUP<br>1642                 |       |               |                                  |
| U.S. PATENT DOCUMENTS   |     |   |      |                               |       |               |                                  |
| EXAM-<br>INER<br>INI-<br>TIAL   |     | DOCUMENT NUMBER   | DATE | NAME                          | CLASS | SUB-<br>CLASS | FILING DATE<br>IF<br>APPROPRIATE |
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| OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)  |     |   |      |                               |       |               |                                  |
|   | AV8 | Hayashi, H. et al., "An Enzyme-linked Immunosorbent Assay for Recombinant Human Tumor Necrosis Factor Using Monoclonal Antibody," <i>Recent Adv. Chemother</i> , 820-821 (1985).                              |      |                               |       |               |                                  |
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